Kennedy/Eshoo Legislation Will Save Lives and Reduce Costs

Thursday, October 29, 2009

The Huffington Post

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Lives and Reduce Costs

By Rep. Anna G. Eshoo (D-Palo Alto)

Like millions of Americans, I was thrilled by today's
unveiling by Speaker Pelosi of the House healthcare reform bill, the Affordable Health Care for America Act. I was proud to stand with the Speaker and my
Democratic Colleagues in support of this historic legislation. Since coming to Congress more than 16 years
ago, nothing has been more important to me than achieving comprehensive
healthcare reform and as a Member of one of the primary committees responsible
for drafting the bill, few Members worked harder than I did in bringing it to
the House Floor.

Ms. Hamsher related some heartbreaking stories about breast
cancer survivors and their struggles to overcome this devastating disease. I've heard dozens of similar stories and each one has moved me to do everything I possibly could throughout my public service
to help breast cancer victims, and I have been a leader in the House of Representatives
in promoting women's breast health. The
National Breast Cancer Coalition, a group representing hundreds of
organizations and millions of women who dedicate their lives to curing breast
cancer has honored me with their prestigious ‘Perfect Voting Record'
honor. I've fought tirelessly to make it
a federal crime for insurance companies to kick women out of their hospital
beds right after they've had a mastectomy (the Breast Cancer Patient Protection Act). I fought for increased access to breast
cancer screening so millions of women can catch the cancer before its too late
(MRI and Mammogram Availability Act).

In 1997, I successfully authored and saw into law the Reconstructive Breast Surgery Benefits Act,
which banned the practice of private insurers treating breast reconstructive
surgery following a mastectomy as cosmetic surgery. In 2000, I was a leading sponsor of the Breast Cancer and Cervical

Treatment Act,
which allows states to use Medicaid dollars to provide health treatment
coverage for low-income women diagnosed with breast or cervical cancer. I also serve as Chair of the Cancer Care Working Group, a coalition of Members in the House who are dedicated to
improving the care and treatment of cancer patients.

I'm exceedingly proud to have legislation I authored many
years ago which prohibits lifetime health insurance caps included in the House
healthcare reform bill. This cap affects
many breast cancer victims, such as the woman mentioned in Jane Hamsher's Huffington Post article, "House Health Care Bill: A Death Sentence for My Fellow Breast Cancer Survivors," effectively
cutting off their insurance when they need it most. My legislation outlaws this practice.

Having put so much into these critical issues, I'm quite
frankly outraged by the falsehoods and misrepresentations in Ms. Hamsher's
article.

My amendment to create a new pathway for approval of
‘follow-on' versions of innovative biotechnology products, or ‘biosimilars,'
will not deny patients access to these miraculous treatments. In fact, my legislation, sponsored by the late Senator Edward Kennedy will create for the first time in our country's
history an FDA approval process for biosimilars to compete with innovative
biologics.

Today, no expedited pathway for approval of a follow-on
version of a biologic product exists.
There are only generic versions of traditional, small-molecule drugs. For biologics, any prospective competitor to a brand-name product would have to go through the same lengthy and expensive approval
process and clinical trials as the original manufacturer. As a result, there is very little economic incentive
to develop a competitive version of a successful biologic.

Under the legislation that Senator Kennedy and I championed,
prospective biosimilar manufacturers would be permitted to use an accelerated
approval process and utilize the clinical trials and laboratory data of the
innovative product to demonstrate the safety and efficacy of their
product. Biotechnology products are highly
complex and, unlike traditional chemical drugs, they cannot be precisely
duplicated by a second manufacturer. Our
amendment would allow these follow-on manufacturers to say, in essence, "my product is close enough to the original product, and the FDA can rely on the innovator's safety and efficacy data to approve my product."

Biotechnology products cost billions of dollars to develop,
test and bring to market, and in order to ensure that competitors aren't
immediately allowed to free-ride on the costly safety and efficacy data
produced by innovators, some period of ‘data exclusivity' is necessary to allow
some period of time to recoup the investment in developing the drug. Without such a ‘data exclusivity' period,

there would be no reason to invest in new biologics. We would see the flow of research funds going to traditional pharmaceuticals, medical devices, semiconductors, green technology or other more promising innovations.

The House and Senate healthcare bills include a data exclusivity period of 12 years, which is the same amount of time that all drugs enjoy on the market under patent protection, which prevents any competition. I believe the 12-year data exclusivity period preserves the existing incentives for investment in these life-saving products.

It's important to note that today there is absolutely no restriction on data exclusivity - it's effectively infinite. Competitors are never permitted to use the data produced by a brand-name biologic manufacturer. The Kennedy-Eshoo legislation brings this exclusivity down from infinity to 12 years, in essence laying the groundwork for the creation of the biosimilar industry, new competition for the biotechnology industry, and reduced prices for patients.

Let me individually address the patently false statements in Ms. Hamsher's post.

"...thanks to Representatives Anna Eshoo and Joe Barton, there will be no generic versions of these drugs. At least not for 12 years..."

The 12-year data exclusivity period in the Kennedy-Eshoo legislation begins from the time of FDA approval. Since the vast majority of the most popular biologics treatments were approved at least 12 years ago, this means that they would have virtually no data exclusivity protection. The important cancer and anemia treatments that millions of patients rely on will be subject to biosimilar competition as quickly as the FDA can process the follow-on manufacturers' applications. (For example, under my amendment Herceptin's data exclusivity period will expire in September 2010.)

"And because of an ‘evergreening' clause that grants drug companies a continued monopoly if they make slight changes to the drug (like creating a once-a-day dose where the original product was three times per day), they will never become generics."

There is no ‘evergreening' clause in my legislation. There is in fact an ‘anti-evergreening' clause which explicitly provides no new exclusivity period would be granted for "a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength." My amendment prohibits by its plain

language exactly what Ms. Hamsher alleges it would encourage.

Finally, Ms. Hamsher seems to be describing an alternative outcome which is pure fiction. She rightly complains about the high cost of many biologic treatments which can run into the tens of thousands of dollars per year, but she seems to indicate that these products would be readily affordable for patients, if only we would subscribe to the proposals of generic drug manufacturers and the insurance companies.

The cornerstone of the Kennedy-Eshoo legislation is to bring down the costs of today's biologics by bringing them into an era of biosimilars, just as Congress moved pharmaceutical drugs to generic drugs.

The House healthcare reform legislation thankfully and finally allows the Secretary of the Department of Health and Human Services to directly negotiate the costs of drugs and biologics for Medicare recipients.

I want to highlight a point on which Ms. Hamsher and I are in complete agreement:

"If an AIDS vaccine is found, it too will be a biologic."

She's absolutely correct - if we develop an AIDS vaccine, a cure for cancer or diabetes, or an effective treatment for Alzheimer's, ALS, Parkinson's or countless other of our most horrific diseases, it will come through biotechnology. Each of these research pathways is difficult and costly, and will require billions of dollars in investment. If we undercut the incentives for this research, who exactly will invest in these life-saving biologics? Will we see companies shifting their resources to developing the next great erectile disfunction drug or cure for baldness?

I'm proud that the legislation that Senator Kennedy and I have worked on for over three years is included in the healthcare reform bills inn both legislative bodies. I'm proud to have this legislation endorsed by: The AIDS Institute, ALS Association, Alliance for Aging Research, American Autoimmune Related Diseases Association, Association of American Universities, Candlelighters Childhood Cancer Foundation, former Vermont Governor Howard Dean, M.D., Immune Deficiency Foundation, the National Alliance on Mental Illness and many other patient advocacy

groups.

Our amendment passed by large bipartisan majorities in the House Energy & Commerce Committee (47 to 11) and the Senate Health, Education, Labor and Pension Committee (16 to 7). It is supported by ten governors who have written to the bipartisan congressional leadership supporting the amendment.

Ms. Hamsher attributes nefarious motives to this effort and the legislation. I fiercely disagree. It was carefully shaped and guided by Senator Kennedy and myself with the highest purposes of bringing life-saving biologics to include biosimilars, to save lives and to bring down the costs to every human being in our country who needs them.